UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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PAMLAB LLC., ET AL,

Plaintiffs,

-against-

SETON PHARMACEUTICALS, LLC.

Defendant.

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OPINION & ORDER

10 Civ. 7680 (KMW)

KIMBA M. WOOD, U.S.D.J.:

Plaintiffs Pamlab, L.L.C. ("Pamlab"), Metabolite Laboratories, Inc. ("Metabolite"), and Breckenridge Pharmaceutical, Inc. ("Breckenridge") (collectively, "Plaintiffs") have moved, pursuant to Federal Rule of Civil Procedure 65, for a preliminary injunction against Defendant Seton Pharmaceuticals, L.L.C. ("Defendant"). Plaintiffs seek to enjoin Defendant from advertising, promoting, offering to sell, or selling its pharmaceutical product Cavan-X in a manner that violates Section 43(a) of the Lanham Act, 15 U.S.C. § 1125 (2006). For the reasons that follow, the Court DENIES Plaintiffs' motion for a preliminary injunction.

Having reviewed the evidence, considered the arguments of counsel, and assessed the credibility of all witnesses, the Court makes the following findings of fact and conclusions of law pursuant to Federal Rules of Civil Procedure 52(a) and 65.

I. Background

A. The Parties and Products

Plaintiff Metabolite Laboratories, Inc. is the owner of United States Patent No. 6,528,496, entitled "Compositions, Treating, Preventing, or Reducing Elevated Metabolic Levels" (the "'496 patent."). Pursuant to a patent license from Metabolite, Plaintiff Pamlab markets Foltx, a medical food product that contains the following three active ingredients: 2 mg. of vitamin B12,

25 mg. of vitamin B6, and 2.5 mg. of folic acid (also known as Folacin). (Pl. Mem. at 4; DeRenzi Decl. Exh. F.) Under a sublicense from Pamlab, Plaintiff Breckenridge markets Folbic as an "authorized generic" for Foltx. Folbic contains the same three active ingredients as Foltx, namely, 2 mg. of vitamin B12, 25 mg. of vitamin B6, and 2.5 mg. of Folic Acid. (Pl. Mem. at 4; see also Lapila Decl. ¶ 6.)

Defendant has manufactured and marketed (since August 23, 2010) a product called Cavan-X. According to Cavan-X's Certificate of Analysis ("COA"), Cavan-X contains the following three active ingredients: 2 mg. of vitamin B12, 25 mg. of vitamin B6, and 2.5 mg. of folinic acid. (DeRenzi Decl. Exh. B.) Thus, although Cavan-X contains two of the same active ingredients as Foltx and Folbic, the third active ingredient in Cavan-X is folinic acid, not folic acid. As Defense Counsel explained to this Court, "[Cavan-X] does not, N-O-T, contain the same ingredients – much less the same ingredients in the same amounts – as the plaintiffs' products … It contains, your Honor, a chemical called folinic, F-O-L-I-N-I-C acid, not folic acid. … There is no folic acid [in Cavan-X.]" (DeRenzi Decl. Exh. A, at 2:24-3:6.)

Foltx, Folbic, and Cavan-X are prescribed medical food products, intended for specific dietary management of individuals under a physician's treatment for hyperhomocysteinemia, a medical condition that increases the risk of artery disease. (Pl. TRO Mem. at 2.) These products have also been described, at various times, as nutritional supplements, dietary supplements, and prescription vitamins. (See Tr. of Hr'g Vol. 3, 325:1 - 327:16, Nov. 3, 2010, Nov. 9, 2010, Nov. 10, 2010.)

B. The Labeling

1. The Initial Cavan-X Label

Although the third active ingredient in Cavan-X is folinic acid, Cavan-X's initial label (the label until mid-November 2010) did not state that Cavan-X contains "folinic acid." Rather, the label listed the third active ingredient in Cavan-X as "Vitamin B9." (Pl. Exh. 9.) On the label, the term "Vitamin B9" is followed by a footnote, stating:

> "Vitamin B9 is a class of folates that includes folic acid and other vitamers – such as reduced folates."

(Id.)

2. The Revised Cavan-X Label

On November 16, 2010, after the preliminary injunction hearing had adjourned, Defendant informed the Court that the Cavan-X label had been revised. (Flood Decl. No. 2 at SP. 0000733 & SP. 0000736.) The revised Cavan-X label continues to list the third active ingredient in Cavan-X as "vitamin B9," but the footnote has been edited to state:

> "Vitamin B9 is a class of folates that includes folic acid and reduced folates such as folinic acid."

(Id. at SP. 0000734 & SP. 0000737.)

C. The Databases

Physicians often prescribe brand name products. When filling prescriptions and purchasing pharmaceutical products, pharmacists often consult one of two standard pharmaceutical industry databases, First DataBank or Medi-Span (the "databases"), to ascertain whether there is one or more generic product that is "pharmaceutically equivalent" to a brand product. (Wechsler Dir. ¶ 13.) Manufacturers of generic products who seek to have a purchaser substitute their generic product for a brand product do so by (1) informing the compiler of a data base (the "compiler") on a "new submission form" that its generic product is "similar to" a particular brand product, and (2) stating the active ingredients in the generic product. (See

DeRenzi Decl. Exhs. G and H.) By stating the active ingredients in its generic product, the manufacturer of the generic product allows the compiler to ascertain whether the generic product is "pharmaceutically equivalent" to the brand product. A product is "pharmaceutically equivalent" to a brand product if it contains the same active ingredients, in the same amounts, as the brand product. ((Lapila Decl. at ¶ 11; Wechsler Decl. ¶ 13.) The compilers rely on manufacturers of generic products to identify the active ingredients contained in their products. (Wechsler Dir. ¶ 15.) Products that are pharmaceutically equivalent are denominated in the industry as "linked" to one another in the databases, which denotes that the generic product is pharmaceutically equivalent to the branded product with which it is linked. (Lapila Dir. ¶ 11; Wechsler Decl. at ¶ 13.)

On September 30, 2010, Defendant submitted a "new product submission" form for Cavan-X to both First DataBank and Medi-Span, stating, "This product is similar to Foltx." (DeRenzi Decl. Exh. G, at SP. 0000001 & Ex. H, at SP. 0000007.) Defendant also stated on the form that Cavan-X's active ingredients were those stated on its "Insert/Label." (DeRenzi Decl. Exh. G, at SP. 0000005 and Ex. H, at SP. 0000011.) As discussed above, the initial Cavan-X label did not mention the actual, active ingredient "folinic acid." Instead, Cavan-X's label read, "Vitamin B9," with a footnote, stating "Vitamin B9 is a class of folates that includes folic acid and other vitamers – such as reduced folates." (Pl. Exh. 9.)

Defendant's submission to at least one database, Medi-Span, resulted in Medi-Span linking Cavan-X to Pamlab's Foltx and Folbic, and erroneously listing "folic acid" as the third of Cavan-X's three ingredients. (See Pl. Exh. 1, at BPI 000255-000257.)

D. Defendant's November 16, 2010 Communications with the Databases[1]

[1] Defendant asserts that Medi-Span and First DataBank are "the only two databases to which it provided the Cavan-X label and product insert." (Def. Post-Hr'g Mem. at 3 n.2.)

As noted above, on November 16, 2010, Defendant informed the Court that it had revised the Cavan-X label. Defendant further informed the Court that it had communicated that revision to Medi-Span and First DataBank. Defendant stated to those databases that "the Cavan-X label is being revised to state that vitamin B9 in Cavan-X is in the form of folinic acid. Ingested folic acid is metabolized into folinic acid." (Flood Decl. No. 2 at SP. 0000733 & SP. 0000736.) In those communications with Medi-Span and FirstBank, Defendant enclosed the "revised label" for Cavan-X.[2] (Id.)

Medi-Span responded to Defendant that day, stating, "We have had a clinical team review this and it appears to be correct in our drug databases file." (Flood Decl. No. 3, Exh. A, at SP. 0000739.)

II. Procedural History

On October 12, 2010, Plaintiffs moved for a temporary restraining order ("TRO") enjoining Defendant from marketing Cavan-X as linked to Foltx and Folbic, based on Defendant's alleged patent infringement and Lanham Act violations. On October 13, 2010, the Court held a hearing on the motion for a TRO, and, after notice to the parties, converted the motion for a TRO into a motion for a Preliminary Injunction ("PI").

On October 14, 2010, Plaintiffs' counsel informed the Court that Plaintiffs were no longer seeking injunctive relief based on their patent infringement claim, because they had learned from Defendant that Cavan-X does not contain the same active ingredients as Plaintiffs' patented product (they had learned for the first time that Cavan-X contains folinic acid, rather

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[2] As mentioned above, the revised Cavan-X label continues to list the third active ingredient in Cavan-X as "vitamin B9," but the footnote has been revised to state: "Vitamin B9 is a class of folates that includes folic acid and reduced folates such as folinic acid." (Id. at SP. 0000734 & SP. 0000737.)

than the folic acid found in Plaintiffs' product). Plaintiffs informed the Court that they were proceeding with their Lanham Act claim.

On October 26, 2010, Plaintiffs filed the instant Motion for a Preliminary Injunction. (See Plaintiffs' Motion for a Preliminary Injunction, Dckt. Entry No. 18.) In the motion, Plaintiffs allege that Defendant, by misrepresenting Cavan-X's active ingredients on the Cavan-X label, is engaging in false advertising in violation of the Lanham Act, causing Plaintiffs irreparable injury. (Pl. Mem. at 1-3.) In their reply brief, Plaintiffs allege a second Lanham Act violation: that the expiration date found on the Cavan-X label constitutes false advertising under the Lanham Act, because that date is not supported by adequate stability testing. (Pl. Reply Mem. at 8-9.)

On November 3, 10, and 11, 2010, the Court held an evidentiary hearing on the motion. On November 16, 2010, the parties submitted post-hearing briefs, in which the Defendant informed the Court that it had revised the Cavan-X label.

III. Applicable Law

A. Preliminary Injunction Standard

"A party seeking preliminary injunctive relief must establish: (1) either (a) a likelihood of success on the merits of its case or (b) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in its favor, and (2) a likelihood of irreparable harm if the requested relief is denied." Time Warner Cable, Inc. v. DIRECTV, Inc., 497 F.3d 144, 152-53 (2d Cir. 2007).

"A preliminary injunction is an 'extraordinary remedy' that should not be routinely granted." Procter & Gamble Co. v. Ultreo, Inc., 574 F.Supp.2d 339, 344 (S.D.N.Y. 2008) (quoting JSG Trading Corp. v. Tray-Wrap, Inc., 917 F.2d 75, 80 (2d Cir. 1990)). "Whether

injunctive relief should issue or not 'rests in the sound discretion of the district court.'" Id. (quoting Reuters Ltd. v. United Press Int'l, Inc., 903 F.2d 904, 907 (2d Cir. 1990)).[3]

B. The Lanham Act

1. Generally

Plaintiffs allege that Defendant has engaged in false advertising in violation of Section 43(a) of the Lanham Act, which provides that:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
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> . . .
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> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

[3] Where a party seeks a "mandatory" preliminary injunction – one that alters the status quo by requiring a defendant to perform a "specific act" – the plaintiff must establish a "clear" or "substantial" likelihood that it will prevail on the merits, rather than simply a likelihood that it will prevail. See Mastrovincenzo v. City of N.Y., 435 F.3d 78, 89-90 (2d Cir. 2006). In the case of a "prohibitory" injunction – one that maintains the status quo by requiring the defendant to refrain from doing something – the applicable test is a "likelihood of success on the merits." Id.

Defendant argues that Plaintiffs' motion should be subject to the higher standard applicable to a "mandatory" injunction, because Plaintiffs are asking the Court to order Seton to take a positive act, namely, to stop selling its Cavan-X product and to make corrective statements to industry databases.

Defendant has misstated the nature of this injunction. Plaintiffs are asking the Court to preserve the status quo prior to the pending controversy. "The status quo to be preserved by a prohibitory preliminary injunction is the last actual, peaceable uncontested status which preceded the pending controversy." Sunrise Dev., Inc. v. Town of Huntington, N.Y., 62 F.Supp.2d 762, 772 (E.D.N.Y. 1999) (quotations and internal punctuation omitted). Defendant started manufacturing and marketing its Cavan-X product to consumers after Plaintiffs initiated the present suit; Defendant was not engaging in that conduct prior to the pending case. Here, Plaintiffs are asking the Court for a prohibitory injunction that would preserve the status quo *ex ante*. Accordingly, the standard for the preliminary injunction analysis is a "likelihood of success on the merits."

shall be liable in a civil action by any person who . . . is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1). Section 24 of the Lanham Act, 15 U.S.C. § 1116(a), gives district courts the "power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable," to prevent ongoing violations of Section 43(a) of the Lanham Act.

Although false advertising claims have traditionally been asserted in the context of statements appearing in television commercials and print advertisements, they have also been asserted in the context of pharmaceutical labeling. See, e.g., Merck Eprova AG v. Brookstone Pharm., LLC, a/k/a Acella Pharm., LLC, No. 09 Civ. 9684 (S.D.N.Y. filed Dec. 15, 2009).

2. Falsity

"To establish a false advertising claim under Section 43(a), the plaintiff must demonstrate that the statement in the challenged advertisement is false." S.C. Johnson & Son, Inc. v. Clorox Co., 241 F.3d 232, 238 (2d Cir. 2001). "Falsity may be established by proving either that (1) the advertising is literally false as a factual matter, or (2) although the advertisement is literally true, it is likely to deceive or confuse customers." Id. (quoting Nat'l Basketball Ass'n v. Motorola, Inc., 105 F.3d 841, 855 (2d Cir. 1997)). The first type of claim is known as a "literally false" or "literally false by necessary implication" claim, and the second type of claim is known as an "implied claim." See Stokely-Van Camp, Inc. v. Coca-Cola Co., 646 F. Supp. 2d 510, 525 (S.D.N.Y. 2009). A plaintiff claiming that an advertisement, although literally true, is nonetheless misleading (an "implied claim"), "must offer consumer data or other extrinsic evidence to show that the audience to which the advertisement is directed is in fact misled." Id.

In the instant case, Plaintiffs assert the first type of Lanham Act claim – that Defendant's advertising is "literally false" or "literally false by necessary implication."[4] To prove literal falsity, a plaintiff must prove that the advertisement contains "a statement, [that] on its face, conflicts with reality." Schering Corp. v. Pfizer Inc., 189 F.3d 218, 229 (2d Cir. 1999). The Court then makes its own assessment of whether the advertisement conveys a message that is "literally true" or "literally false." Hertz Corp. v. Avis, Inc., 867 F. Supp. 208, 212 (S.D.N.Y. 1994). "The Court may rely on its own common sense and logic in interpreting the message of the advertisement. . . . The Court need not refer to consumer surveys when an advertising claim is alleged to be literally false on its face." Id. at 212. When an advertisement is proven to be literally false on its face, "consumer deception is presumed, and 'the court may grant relief without reference to the advertisement's [actual] impact on the buying public.'" Time Warner, 497 F.3d at 153 (quoting Coca-Cola Co. v. Tropicana Prods., 690 F.2d 312, 317 (2d Cir. 1982)).

As discussed above, a plaintiff can also establish literal falsity by proving that an advertisement is "literally false by necessary implication." Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 946 (3d Cir. 1993). "Under [this] doctrine, a district court evaluating whether an advertisement is literally false must analyze the message conveyed in full context, [and] it must consider the advertisement in its entirety and not ... engage in disputatious dissection." Time Warner, 497 F.3d at 158 (internal citations and quotations omitted). "If the words or images, considered in context, necessarily imply a false message, the advertisement is literally false and no extrinsic evidence of consumer confusion is required." Id.; see also Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Pharm. Co., 290 F.3d 578, 586-87 (3d Cir. 2002) ("A

[4] Although the parties have recently suggested that Plaintiffs are also bringing an "implied claim," (see Def. Post-Hr'g Mem. at 7-10; Pl. Post-Hr'g Mem. at 9-10,) they are not. Plaintiffs have pled only the first type of Lanham Act claim – a literally false or literally false by necessary implication claim.

literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.") (quotations omitted). "However, 'only an *unambiguous* message can be literally false.'" Time Warner, 497 F.3d at 158 (quoting Novartis, 290 F.3d at 587.) "Therefore, if the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." Id. See also Stokely-Van Camp, 646 F. Supp. 2d at 525 ("[W]here the language of an advertisement is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false.") (quotations omitted).

3. Materiality

Under either theory of falsity, "the plaintiff must also demonstrate that the false or misleading representation involved an inherent or material quality of the product." Id. at 153 n.2. "This requirement is essentially one of materiality." S.C. Johnson, 241 F.3d at 238. Once a statement is determined to be false, the information contained in the statement is presumed to be material. Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp., 348 F.Supp.2d 165, 180 (S.D.N.Y. 2004).

IV. Application of Law to Fact

A. Likelihood of Success on the Merits

To obtain injunctive relief, Plaintiffs must show a likelihood of success on the merits of their false advertising claims.

1. Ingredients Listed on the Cavan-X Label[5]

[5] Here, the Court is discussing the initial Cavan-X label, rather than the revised Cavan-X label, because bottles of Cavan-X bearing the initial label are out in the marketplace. The Court will discuss below what impact, if any, the revision to the Cavan-X label has on our analysis. See infra, pages Section IV.A.1.b.

With regard to the ingredients listed on the initial Cavan-X label, Plaintiffs allege falsity under the first theory, literal falsity. Plaintiffs make two related but distinct arguments. First, Plaintiffs argue that, in failing to identify folinic acid as one of Cavan-X's ingredients, Defendant has made a false statement as to an active ingredient contained in Cavan-X. (Pl. Mem. at 1-2.) This is evidenced, Plaintiffs contend, by the fact that one of the databases (Medi-Span) lists Cavan-X as containing the active ingredient folic acid, when, in fact, Cavan-X contains folinic acid. (Pl. Exh. 1.) Second, Plaintiffs assert that vitamin B9 is folic acid, and folic acid alone; it is not folinic acid. Plaintiffs contend that Defendant's statement is literally false, because Cavan-X contains folinic acid, not folic acid. In response, Defendant asserts that the term "Vitamin B9" refers to "folates", and that the family of folates includes both folic acid and folinic acid. Therefore, Defendant contends, listing folinic acid as "vitamin B9" is not a literally false statement.

Although reference to the term "folic acid" may cause consumers to believe that Cavan-X contains folic acid, on this record, the Court's task is to decide whether Defendant made a literally false statement on the Cavan-X label. Plaintiffs have not shown that it is literally false for Defendant to use the group label of "vitamin B9" or "folates" to describe a specific member of that group, folinic acid.

Both parties and their experts agree that the term "folates" refers to a group of chemical compounds, and that that group includes both folic acid and folinic acid. Plaintiffs' own expert, Dr. David Bugay, a Ph.D. chemist with over 22 years of experience in the analysis of pharmaceutical drug substances, explained that "there is a class of compounds that are referred to as folates, and within that class there are individual compounds …." (Tr. vol. 1, 78:20-22.) Dr. Bugay then testified that one of the individual compounds found in the class of "folates" is

"folinic acid". See Tr. 91:21-22 ("[F]olinic acid . . . is in the class of folates."). See also id. 92:21-22 ("Folic acid and folinic acid are in the class of folates."). Moreover, for three of their own pharmaceutical drug products, Plaintiffs themselves designate "folate" as one of the active ingredients in those products.[6] (Def. Exh. A. at BPI 000253.)

(a) Assertion that Vitamin B9 Has Only One Constituent – Folic Acid

Recognizing that the term "folates" includes the specific compound of folinic acid, Dr. Bugay attempted to rest the falsity argument on the fact that the term "vitamin B9" consists only of "folic acid," and that, it is therefore literally false to state that vitamin B9 is a class of folates, and to thereby equate "vitamin B9" with "folinic acid." (Tr. 81:1-82:3.)

However, Defendant's own expert, Dr. Irwin Harold Rosenberg, a physician and scientist specializing in medicine and nutrition, and a professor at Tufts University, explained that "[t]he common usage of vitamin B9 . . . is often used to refer to [a] . . . family of compounds [which] . . . includes folinic acid." (Rosenberg Decl. ¶ 7.) Dr. Rosenberg further explained that "[f]olate is the general term for the B-group vitamin (vitamin B9) . . . [and that] folic acid and folinic acid . . . are both folates." (Id. at ¶ 9.) Finally, he made clear that "folate and folic acid are both . . . forms of vitamin B9." (Id.)

Moreover, Dr. Bugay cited as support for his assertion that vitamin B9 consists only of folic acid, the Merck Index and a DrugBank report, neither of which actually supports his assertion.[7] Although the Merck Index makes it clear that folic acid and folinic acid are distinct

[6] When asked by defense counsel about Plaintiffs' use of the term "folate" on three of their own products, Dr. Bugay attempted to distinguish between the singular use of "folate" and the plural use of "folates." Specifically, he stated that, when used in the singular, "folate" refers to the specific compound folic acid, but that "when it says folates in the plural, that refers to a class of compounds." (Tr. at 89:1-3.) The Court is not persuaded by this semantic distinction.

[7] Dr. Bugay described the Merck Index as a "universally recognized, authoritative reference book for the pharmaceutical industry that identifies various active pharmaceutical ingredients

chemical compounds, it does not discuss the term "vitamin B9" or "folate." (See Bugay Dir. Exh. 3.) Therefore, it does not illuminate whether "vitamin B9" denominates only folic acid. The DrugBank Report (the "Report") includes an entry for "Folic Acid." (See Bugay Dir. Exh. 5.) In that entry, the Report lists "vitamin B9" as one of several synonyms for the term "folic acid." (Id.) However, the fact that the term "vitamin B9" may be treated as synonymous with the term "folic acid," sheds no light on whether the term "vitamin B9" may also be synonymous with the term "folinic acid." When Dr. Bugay was asked whether he had read any literature on folates, outside of the Merck Index and the DrugBank report, he responded that he had not. (Tr. 82:18-23.)

Finally, Dr. Rosenberg was asked whether, if he were labeling Defendant's product, he would label the compound "folinic acid" as "vitamin B9." (Id. at 124:13-15.) He responded, "I might not – but I don't consider it inappropriate because I think vitamin B9 means folate." (Id. at 124:18-20.) When asked directly whether the footnote following the Cavan-X label is "an accurate statement," Dr. Rosenberg responded that it is, because he "think[s] vitamin B9 is the name of the class [of folates.]"[8] (Id. at 142:1-8.)

The Court notes that Defendant could easily have properly identified the third active ingredient in Cavan-X as folinic acid.[9] It appears that there was no reason for Defendant not to

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and related materials." (Bugay Dir. ¶ 16.) He described DrugBank as "a knowledgebase for pharmaceutical products, drug actions and drug targets." (Id. at ¶ 13.)

[8] This is true notwithstanding the fact that Dr. Rosenberg testified that "if [he] prescribed folic acid, that is what [he] would expect the pharmacist to put [in]." (Tr. 132:15-16.) Dr. Rosenberg's personal preferences as a prescribing physician do not undermine his testimony that B9 is an acceptable substitute for folic acid.

[9] The testimony makes clear that, for certain populations, folic acid and folinic acid can have different impacts on the human body, and that there remains more to be learned regarding possible differences between the two compounds. (See Tr. 109:24-110:1.) For this reason, a treating physician – through a pharmacist – would likely prefer to know that, when he/she

identify it as folinic acid, other than Defendant's desire to bolster its claim that Cavan-X is "similar to" – and thus should be "linked to" – Plaintiffs' products.

However, a Lanham Act claim cannot rest on the lack of specificity alone. Plaintiffs have not shown that it is literally false to use the group label of "vitamin B9" and "folates" (accompanied by the footnote "Vitamin B9 is a class of folates that includes folic acid and other vitamers – such as reduced folates") to denominate a specific member of that group, folinic acid.

Nor can Plaintiffs rely on the doctrine of falsity by necessary implication. Time Warner cautions that the doctrine of "false by necessary implication" can be applied only to unambiguous language. "[I]f the language … is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." Time Warner, 497 F.3d at 158. As is clear from the testimony of both parties' experts, the terms "vitamin B9" and "folates" are ambiguous group labels, and susceptible to more than one reasonable interpretation.

(b) The Revised Cavan-X Label

As discussed above, the revised Cavan-X label now denominates both "folinic acid" and "folic acid" as members of the vitamin B9/folates group. (Flood Decl. No. 2 at SP. 0000734.) In sending the revised label to the databases, Defendant specifically communicated to the compilers that the "vitamin B9 in Cavan-X is in the form of folinic acid." (Id. at SP. 0000733.) It appears that Medi-Span will continue to link Cavan-X to Foltx and Folbic. Indeed, Medi-Span responded to Defendant that day, stating, "We have had a clinical team review this and it appears to be correct in our drug databases file." (Flood Decl. No. 3, Exh. A, at SP. 0000739.)

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prescribes either folic acid or folinic acid to a particular patient, the prescription will be filled as written. In order to do this, physicians and pharmacists would likely expect to be able to rely on industry databases to state the specific ingredients contained in a specific product. However, for the reasons described above, the Lanham Act does not require labeling to be that specific – it does not protect against lack of specificity.

Defendant's revision to the Cavan-X label, and the databases subsequent response, renders the revised label less ambiguous than the original label.[10]

2. The Expiration Date Listed on the Cavan-X Label

Plaintiffs also allege that the August 2012 expiration date found on the Cavan-X label constitutes literally false advertising under the Lanham Act, because that date is not supported by adequate stability testing. (Pl. Reply Mem. at 8-9.) Although the Cavan-X label says nothing about what kind of stability testing was performed to support the expiration date, Plaintiffs contend that, by affixing a two-year expiration date on Cavan-X's label, Defendants have represented that appropriate stability testing has been performed to support the expiration date listed on Cavan-X. (Pl. Reply Mem. at 9; Pl. Post-Hr'g Mem. at 12.) Plaintiffs refer to the expiration date as "an establishment claim," meaning that Defendant, by affixing an expiration date on the Cavan-X label, has represented that sufficient stability data supports that expiration date. (Pl. Post-Hr'g Reply Mem. at 5.)

[10] Plaintiffs acknowledge that Defendant has changed its label, but argue that this change only "continues Seton's misrepresentations of Cavan-X with false and misleading statements." (Pl. Post-Hr'g Reply Mem. at 1.)

Plaintiffs also note that Medi-Span and First DataBank continue to link Defendant's product to Plaintiffs' products. (Id.) Plaintiffs direct the Court to Medi-Span's "Documentation Manual," which defines as "pharmaceutically equivalent" those drug products that are "identical" in terms of "active ingredients." (DeRenzi Supp. Decl. No. 2, Exh. C, at WKPN 036.) Plaintiffs thus appear to be suggesting to the Court that Defendant's label change is insufficient, because the linkage between Cavan-X and Plaintiffs' products persists, and thus violates Medi-Span's own Documentation Manual. For this reason, Plaintiffs request the opportunity to submit additional evidence from the databases as it becomes available, (Pl. Post-Hr'g Reply Mem. at 1,) and to file a short supplemental brief on the databases' response to Defendant's label change. (Pl. Letter Nov. 22, 2010.)

The Court's task in addressing Plaintiffs' Lanham Act claim as currently asserted is to determine whether the statement contained on the Cavan-X label is literally false or literally false by necessary implication, not whether Defendants are making an "implied claim" that results in consumer confusion. The Court has found that the statement on the label is not literally false, nor literally false by necessary implication.

Defendant contends that it relied on the stability testing done on products similar to Cavan-X when it included the expiration date on Cavan-X's label. (Conf. Tr., 5:2-6, November 1, 2010.) Defendant further contends that it has begun accelerated and real time stability testing on Cavan-X to verify the two-year expiration date.[11] (Conf. Tr., 5:13-14.) Defendant has informed the Court that its three months of accelerated stability testing would be complete on November 27, 2010. (Def. Post-Hr'g Mem. at 20.) Defendant has not told the Court the results of that testing.

Plaintiffs argue that the testing already done by Defendant is not satisfactory, because (1) performing stability testing on a product similar to Cavan-X (as Defendant has done), rather than a product identical to Cavan-X, is not supported by common industry practices; and (2) the results from the first two months of Defendant's accelerated stability testing on Cavan-X do not support the expiration date, because significant degradation has occurred in the product during that testing. (Pl. Post-Hr'g Mem. at 12-13; Pl. Exs. 7 & 8.) Plaintiffs argue that Cavan-X must undergo an accelerated testing period of six months, rather than three months, to ascertain whether the degradation is in an acceptable range. (Pl. Post-Hr'g Mem. at 13.)

Both parties agree that there is no requirement, by the Food and Drug Administration (the "FDA"), or any other regulatory body, that a product like Cavan-X include an expiration date on its label. (Tr. vol. 2, 258:8-23.) However, the parties also acknowledge that, if an expiration date is included on a product label like that on the Cavan-X label, that date "must be scientifically justified with experimental data." (Tr. 255:2-3; Pl. Post-Hr'g Mem. at 12; Def Post-Hr'g Mem. at 18.)

[11] All parties agree that satisfactory results following (1) three months of accelerated stability testing on Cavan-X, or (2) two years of real-time stability testing on Cavan-X, could support Defendant's expiration date. (See Pl. Reply Mem. at 3.)

Plaintiffs allege that "[t]here is no support in industry practice … for Seton's claim that it is acceptable to rely on stability data from tests on … 'similar' products that do not include the same active ingredients." (Pl. Post-Hr'g Mem. at 12.) Plaintiffs had two expert witnesses testify to this effect. (Tr. 253:13-20; 294:4-295:25.) Dr. Bugay testified that he has "never encountered" any situation in which an expiration date was set on a product, based on stability data on another product that did not share identical ingredients. (Id. 253:13-20.) Dr. Reidinger, Associate Director of Regulatory Affairs and Quality Assurance at Breckenridge, testified that stability testing for a product can be done on a similar product, but she stated that, by "similar," she means that the product contains "identical ingredients." (Id. 294:1-10.)

Defendant's expert witness, Dr. Sherry Xie, Chief Scientific Officer and Research and Development Director at Viva Manufacturing (which is manufacturing Cavan-X for Defendant), testified that, in her experience in determining expiration dates, she often uses stability testing of similar products for an expiration date on a new product. (Tr. 236:8-23.) Dr. Xie also testified that she follows the ICH guidelines,[12] which "accept the experience on the stability test. . . . [t]he experience [of] similar product[s]." (Tr. 236:19-23.)

None of the experts has had broad enough experience to render his or her testimony on this issue dispositive. The Court notes that the FDA has encountered a similar issue with respect to the expiration date testing of "dietary supplements," and that the FDA has found that the views of commentators on that issue were far from uniform. In "Current Good Manufacturing

[12] "ICH" stands for the "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use."

Practice ("GMP") in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," [13] the FDA explains that,

> "Because the final rule does not require that you establish an expiration date, we decline to offer guidance on the type of data that are acceptable to support an expiration date, other than to repeat that any expiration date that you place on a product label (including a "best if used by" date) should be supported by data."

72 Fed. Reg. 34752-01, 34856 (2007). The commentators submitted suggestions by people in the industry as to the types of data that should be required to support an expiration date. (Id.) The suggestions varied from strict stability testing to reliance on experience with similar products:

> Many comments state an expiration date on a label must be supported by a rationale or data on stability testing. Some of those comments suggest that manufacturers should have flexibility in the type of supporting data used. Although label claims should be confirmed by shelf life testing when analytical methods exist, data could come from a manufacturer's experience with the product or accelerated stability testing on similar products with the same storage container.

Id.

To show a likelihood of success on the merits with regard to this particular Lanham Act claim, Plaintiffs must show that it is literally false to place a two-year expiration date on the Cavan-X label. Because the Cavan-X label says nothing about what kind of stability testing was performed to support the expiration date, Plaintiffs are relying on an establishment claim theory, and thus can prove literal falsity only by showing that the stability testing done on Cavan-X is insufficient to support the expiration date given. Plaintiffs have failed to meet their burden.

[13] The Court recognizes that the parties have never come to an agreement as to whether medical food products (such as Foltx, Folbic, and Cavan-X) can be referred to as "dietary supplements." However, the Court is not relying on these regulatory provisions to assess the science behind Defendant's expiration date and accompanying stability testing, but rather, to understand analogous common industry practice. The Court notes that both parties have cited the GMP. (See Def Post-Hr'g Mem. at 18; Pl. Post-Hr'g Mem at 12.)

Plaintiffs have failed to show that, when an expiration date is based on stability testing done on a similar product, that similar product must have active ingredients identical to those in the product affixed with the expiration date. The parties' experts disagree on that assertion, and the little regulatory guidance that there is on the topic[14] indicates that such a requirement does not exist.[15]

Because Plaintiffs have not demonstrated a likelihood of success on the merits on both of their Lanham Act claims, the Court DENIES Plaintiffs' motion for a preliminary injunction.[16]

V. Conclusion

For the foregoing reasons, Plaintiffs' motion for a preliminary injunction is hereby DENIED.

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[14] In fact, the regulatory guidance is such that, if Defendant were to remove an expiration date from any future Cavan-X label, Plaintiffs would no longer have this specific Lanham Act claim, because there is no requirement that Defendant affix an expiration date on its Cavan-X product.

[15] As discussed above, Plaintiffs also argue that the results from the first two months of Defendant's accelerated stability testing on Cavan-X do not support the expiration date, because significant degradation has occurred in the product during that testing. (Pl. Post-Hr'g Mem. at 12-13.) Specifically, Plaintiffs allege that the results from the accelerated stability testing thus far "show more than a 10% degradation for folinic acid and more than a 13% degradation for Vitamin B6." (Pl. Post-Hr'g Mem. at 13.) Accordingly, Plaintiffs argue that Cavan-X must undergo an extended testing period of six months to ascertain whether the degradation is in an acceptable range. (Pl. Post-Hr'g Mem. at 13.)

Plaintiffs' and Defendant's experts strongly disagree as to how one measures degradation in a given product, and as to what percentage of degradation is appropriate. (See Def. Post-Hr'g Reply Mem. at 6-7.)

The Court has already determined that the expiration date contained on the Cavan-X label is not literally false, because Plaintiffs have failed to show that the testing done by Defendant on a product similar to Cavan-X is insufficient to support that expiration date. Accordingly, the Court need not decide at this point in time whether accelerated testing was completed in three months (on November 27, 2010), or will be completed in six months. The Court notes that either way, the issue of expiration date may very well be mooted if and when this case proceeds to trial.

[16] Because Plaintiffs have not demonstrated a likelihood of success on the merits on their Lanham Act claims, the Court does not need to reach the issue of irreparable injury.

In light of this denial, IT IS HEREBY ORDERED that the parties shall appear for a status conference on January 10, 2011, at 2:30 p.m. The parties shall submit a joint status report, and a proposed agenda for the January 10 conference, no later than January 5, 2011.

SO ORDERED.

Dated: New York, New York
December 6, 2010

Kimba M. Wood
United States District Judge